01-11-00 Af/Gau 3734

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Lixiao Wang et al
Application No.:	08/685,338
Filed:	July 23, 1996
For:	HIGH COMPLIANCE, HIGH STRENGTH CATHETER BALLOONS USEFUL FOR TREATMENT OF GASTROINTESTINAL LESIONS
Examiner:	Cris L. Rodriguez
Group Art Unit:	3306

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-5902

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
7 pg. Reply Brief in triplicate; VAS Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ☐ Attached is check(s) in the amount of $
   - ☒ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: January 10, 2000

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Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as EXPRESS MAIL EL451220298us, addressed to Box AF, Assistant Commissioner for Patents, Washington D.C. 20231, on January 10, 2000

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JODI A NICKEL

S. Little 1-19-00

PATENT

#24/Reply Brief

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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noted 4/12/00

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REPLY BRIEF

This Reply Brief is submitted in response to the Examiner's Answer mailed November 10, 1999. The Examiner's points of argument will be addressed according to the grouping of claims.

Issue I:

Claim 11

In the Examiner's Response to Applicant's Arguments, it is asserted that "Product by Process Claims" are not limited to the manipulations of the recited steps, but only the structure implied by the steps. It is further stated that, "[i]f the product in the product-by-process claim is the "same" or "obvious" from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." This assertion is made in support of Examiner's *anticipation* rejection to claim 11, which states in it *entirety* that "Anderson et al. discloses a thermoplastic material balloon, where the thermoplastic polymer material is a block

copolymer material."

While it is true that claim 11 provides a balloon wherein "the thermoplastic polymer material [is] a block copolymer material", Examiner ignores what is being done to the claimed material to form the final balloon product. It is this final product which is being compared to the final product of Anderson et al. For this anticipation rejection, it is being asserted that because claim 11 provides a balloon made from a block copolymer material and because Anderson et al. provides a balloon made from a block copolymer material, claim 11 should be rejected for producing a balloon which is identical to the balloon of Anderson et al. This assertion is flawed because claim 11 provides steps which imply a certain change in structure, which must not be ignored, as stated in Examiner's Response to Argument (Paragraph 11, lines 5-6), wherein it is stated that "Product by Process Claims are not limited to the manipulations of the recited steps, *but only the structure implied by the steps*".

Anderson et al., the reference cited in the anticipation rejection, even contradicts this assertion which Examiner bases her rejection upon. Anderson et al. teaches that a physically different balloon may be made by incorporating a "heat set" step, thereby crystallizing the material of the balloon. The patent does not stop in describing its resulting balloon by merely reciting the material, rather it describes the resulting physical characteristics through the formation steps which are used to create the balloon, i.e., the "heat set" step. The patent does not teach a mere *manipulation* of steps applied to the starting material, it teaches at least one notable step which implies a specific alteration in the structure. It is asserted in Anderson et al. that "[t]he balloons formed using the process...will have an overall advantageous combination of **physical** properties...superior to those exhibited by the "compliant" balloons currently available." The heat set step taught by Anderson et al. clearly is used to contribute to these physical properties.

Applicant's claim 11 also provides alterations in the structure of the starting material which are "implied by the steps", as proven by Applicant's experimental data, wherein the steps are distinctly different from those of Anderson et al. As such, an anticipation rejection

cannot be sustained based merely on similarity in starting material. To "determine patentability based on the product itself", weight must be given to process steps which alter the physical nature, or "imply the structure", of the material being used. Such is the attention which must be paid to the "heat shrink" step of claim 11.

Claim 11 requires the step of "annealing the balloon at a second elevated temperature **less** than the first elevated temperature and a second pressure **less** than the first elevated pressure for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter." This language of the claim should be given weight when comparing the characteristics of the claimed final product with the product of the prior art. The method alters the characteristics of a balloon made from "the block copolymer material" as compared to a balloon which is formed by method excluding this second step.

The question is not whether the claimed invention is a balloon made out of a block copolymer. Rather, the focus should be drawn to the structural effects the individual steps have on the starting material and how these effects are exhibited in the final product. As mentioned above, Anderson et al.'s heat set step has been given credit for it's effect on the structure of the final product. Similarly, Applicant's heat shrink step, which has been shown in Applicant's Brief on Appeal to require distinctly different parameters from those of Anderson et al.s' heat set step, must be given similar weight in determining the structure of the final product. In fact, through Applicant's examples, it has been demonstrated that the addition of the heat shrink step does have an effect on the characteristics of a balloon made from the block copolymer material. As such, an anticipation rejection cannot be given based on the notion that both final product are balloons and both processes use similar starting material.

It is not fully understood what is further stated in Examiner's Response to Argument in the sentence starting on page 8, line 4, and ending on line 7. It appears that the sentence has been truncated. However, it has been shown by Applicant that the heat set step of Anderson et al. is markedly different from the heat shrink step of claim 11, both having different physical effects on the starting material, resulting in structurally different balloons.

It is further stated by the Examiner (page 8, line 7) that "[o]bviously, applying a different second elevated temperature would have been an obvious variation from the product of the prior art", that being Anderson et al. This statement contradicts the anticipation assertion. Anderson et al. teaches a second step, the heat set step, which affects the physical structure of the balloon. Examiner states that Applicant's application of a second elevated temperature in its claimed second step, the heat shrink step, produces a balloon which is an obvious variation of the balloon of Anderson et al. If the product of claim 11 is a variation of the product of Anderson et al., an anticipation rejection cannot stand. The resulting products are admittedly different in structure in one way or another.

It is further not seen how or why Applicant's difference in process steps would be an obvious variation from the process of Anderson et al. (Page 8, lines 7-8, of the Examiner's Answer.) Anderson et al. specifically teaches away from the heat shrinking step of the present invention and at the same time claims that the improved properties of its balloon result from the method or process it teaches to form the balloons (see abstract and col 6, lines 13-23 and lines 29-32). It is asserted in Anderson et al. that "[t]he balloons formed using the process...will have an overall advantageous combination of **physical** properties...superior to those exhibited by the "compliant" balloons currently available." The heat set step taught by Anderson et al. clearly is used to contribute to these physical properties.

In the second heat step of Anderson et al., instead of reducing the temperature relative to the first heat step, as required by the present invention, it requires that the temperature in the second step be *increased.* As such, it cannot be presumed, in view of the comparisons shown in the Applicant's specification, that different processes of production applying different parameters would produce balloons that are physically the same. It certainly cannot be said that Applicant's method steps used to created the claimed product are an "obvious variation". Claim 11 specifically directs one to go in the *opposite* direction by requiring in the second step that the balloon be heated to a temperature **less** than the first elevated temperature, thus "heat shrinking" the balloon. This results in a more compliant balloon and, as mentioned above, a physically different balloon.

In the process of Anderson et al., after formation of the balloon, the balloon is heated under pressure of 100-500 psi to a temperature **above** the blowing temperature specifically for the purpose of stabilizing/crystallizing the balloon **against shrinkage upon cooling**. The present invention is directed to exploitation of shrinkage behavior in order to increase and extend the compliance of the resulting balloon. The entire Anderson et al. patent teaches the heat step at an increased second temperature, relative to the initial blowing temperature. This difference is not indicative of an obvious variation.

Applicant has thus shown that the subject claims do incorporate steps which imply structure and therefor should not be ignored in a comparison with products of the prior art. It is further shown that these differences in steps are not mere obvious variations of the prior art steps. Therefore, the rejection should be overturned.

Issue II:

Claims 12-17, 35-42, 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose all the different variations of inflation pressure and diameter as claimed.

Examiner does not specifically address these claims in her Response to Applicant's Argument beyond her discussion about the patentability of claim 11. As such, in addition to the Applicant's Brief on Appeal arguments with regard to the rejections to these claims, Applicant further offers the above arguments directed toward Examiner's additional comments concerning the patentability of the subject matter of claim 11. Since the rejection to these claim depends on Examiner's arguments for the rejection of claim 11, for the above mentioned reasons, similarly, these rejections, which are the subject of Issue II, should be overturned.

Further, there is no indication or citing why the unique set of parameter incorporated in the presently rejected claims would have been obvious in light of Anderson et al. They exhibit separate features of the combination of high compliance and high wall strength for

specifically sized balloons, as well as high burst pressures, which in fact are not suggested in the prior art or previously attainable. As such, overruling of the rejection is respectfully requested.

Issue III:

Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,344,400 to Kaneko et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose the balloon formed from at least two concentric layers of different thermoplastic polymers. However, it is asserted that Kaneko et al. teaches a balloon having the missing limitation, and that it would have been obvious to combine the two reference making claim 43 obvious.

In response, as with Issue II, Applicant asserts that Anderson et al. does not disclose the invention substantially as claimed, and therefore the rejection fails. Claim 43 depends upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40 in *Issue II*, Anderson et al. does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejection be overruled.

Issue IV:

The Examiner also rejects claims 46 and 47 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,167,239 to Cohen et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant. However, it is asserted that Cohen et al. teaches a device having the missing limitation, and that it would have been obvious to combine the two reference making claims 46 and 47 obvious.

In response, Applicant asserts that Anderson et al., again, for the reasons mentioned above, does not disclose the invention substantially as claimed, and therefore the rejection fails. Claims 46 and 47 depend upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson et al. does not disclose the invention

substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejections be overruled.

CONCLUSION

In light of the above comments and in light of the previously filed Appeal Brief, the rejection of claim 11 under 35 U.S.C. §102 and of claims 12-17 and 35-47 under 35 U.S.C. §103(a) must be reversed as being clearly erroneous. It is respectfully requested that the Board of Patent Appeals and Interferences reverse all of the outstanding rejections and pass the application to issue.

Respectfully submitted,

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Dated: January 10, 2000

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